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April 28, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Comments on Proposed Good Guidance Practice Regulations, Docket No. 99N-4783

Dear Sir or Madam:

On behalf of the Indiana Medical Device Manufacturers Council and the Medical Device Manufacturers Association, we would like to offer comments on the Food and Drug Administration's (FDA) proposed rule codifying its policies and procedures for the development, issuance, and use of guidance documents. The Health Industry Manufacturers Association supports these comments, and is filing additional comments of its own.

At the outset, we would like to compliment FDA on the strides the agency has made over the last five years in enhancing its guidance development process. In particular, FDA has made effective use of its website to disseminate draft and final guidance documents. People who live and work far from Rockville have been able to keep current and offer comments much more conveniently as a result. Also, we believe the overall quality of most guidance documents has increased substantially in terms of clarity and content. The recent survey conducted by Price Waterhouse Coopers and the University of California at San Diego confirms that belief. In addition, the publication of a guidance development agenda has been useful, as has the periodic list of completed guidance. We also believe that the agency has made good use of the Good Guidance Practices (GGPs), avoiding podium policy most of the time. From our device industry background, we think the Center for Devices and Radiological Health (CDRH) has shown particular leadership in implementing these improvements.

While we are generally quite pleased with the direction FDA has been headed, we do have some comments on ways in which the proposed regulations can be improved. They fall into nine categories. For each category of improvement, in the title we cite the part of the proposed regulation most implicated.

I. Pre-Proposal Collaboration (Proposed § 115(g)(1)(i))

FDA's willingness to solicit and listen to the input of stakeholders before publishing a draft guidance (and before the agency becomes too invested in a particular proposal) is essential. FDA should provide stakeholders with opportunities to engage in real time dialogues with FDA personnel to discuss issues in need of resolution before the agency even puts pen to paper. We believe such dialogues will prove much more useful to the agency (and to the industry) than the iterative input obtained in a notice-and-comment proceeding, which occurs only after FDA personnel have become wed to a proposed draft.

A number of possible avenues exist for pre-proposal collaboration. A few examples include:

(1) joint FDA/industry task forces (similar to the joint working group of industry and CDRH representatives that examined the product development protocol process);

(2) standards activities organized by appropriate standards development organizations (§ 10.95);

(3) public meetings, including FDA workshops, conferences, etc. (§ 10.65(b));

(4) private meetings with specific industry groups on FDA's premises (§10.65(d));

(5) industry-hosted meetings that FDA attends (§ 10.65(e));

(6) continuing meetings without uniform composition;

(7) Capitol Hill-convened meetings;

(8) meetings convened by a neutral third party (*e.g.,* FDLI, as they did in the inspection technique project);

(9) written pre-proposal dialogue, either e-mail or other correspondence (§10.65(f)); and

(10) as part of an advisory committee meeting.

Given today's information technologies, many of these avenues would not require that the agency and interested stakeholders be in the same room. For example, the dialogues could take place via telephone conference calls, video desktop conferencing, electronic chat rooms, or various types of Internet broadcasting.

These possible avenues are the subject of discussion currently between industry and FDA. We think FDA ought to set as a goal developing a guidance document that identifies several specific techniques that the agency may use to collaborate.

With respect to the rule-making, FDA should ensure that the proposed rule is broad enough to permit a wide range of these types of pre-proposal collaborative sessions to ensure the development of informed guidance documents, and to expressly recognize the benefit of collaboration. As a part of that, FDA should cross-reference some of the interactive approaches referenced above, but also make it clear that the list is not exhaustive.

II. Post-Proposal Collaboration (Proposed § 115(g)(1)(iii) and (g)(4))

FDA should be able to use the same techniques suggested for pre-proposal collaboration once a proposed guidance is released in draft form, but before it is put in final. While interactive techniques clearly are better when they occur before the release of the first draft, there may be instances where a particular draft generates controversial issues that can be best addressed interactively. The regulations should specifically contemplate and permit that kind of real time interaction occurring between the draft and final versions of guidance documents.

III. Prioritizing Guidance and the Guidance Development Agenda (Proposed § 115(f)(4))

We believe there needs to be a better system for prioritizing (1) topics for the agency to address in new guidance documents, and (2) the revision of existing guidance documents. Because guidance development requires significant agency resources, in some cases FDA may want to know where the industry would value guidance the most.

Industry has not done a good job of offering input, other than offering occasional casual input to FDA representatives at public gatherings. FDA should consider whether there are structural improvements that may encourage industry input on setting priorities.

An important tool in offering input on priorities is the guidance development agenda. FDA has proposed publishing that agenda only once per year, instead of twice. The document lists possible topics (from FDA's viewpoint) for future guidance development. Among other things, the agency suggests that publishing the agenda is a burden and that the agenda does not change much during the course of a year.

We believe that the agency's agenda changes quickly enough to merit twice-a-year publication. FDA's rulemaking agendas — which the agency publishes twice a year — demonstrate how dramatically things can change. Moreover, informal contact with the agency tells us that the agency's thinking evolves quickly enough that an annual guidance agenda would not suffice.

FDA might ease its burden by not publishing these agendas in the *Federal Register*, but instead simply posting them on the agency's website. That way, the administrative burden is essentially conducting an internal e-mail survey of the relevant FDA offices asking them to list their potential topics, and then electronically posting those topics on the website. Indeed, we understand that FDA already does much of this work as part of its efforts to manage the guidance development process, so the additional effort of posting the information on the website should be minimal. Using the website may also lead to agency to release the information sooner, when it is more likely to be useful. That

agenda could be broadened into a tracking system that keeps the public and agency up to date on the status of guidance under development

In a related vein, we also suggest that FDA consider more interactive techniques for soliciting input on priorities that might include town hall meetings and the like. FDA should also make the agenda more user friendly by separating the guidance on cross-cutting issues (horizontal guidance) from technology-specific guidance (vertical guidance). The vertical guidance could be organized more clearly into technology categories.

IV. Responses to Comments (Proposed § 115(g)(1)(iv))

FDA, in developing its GGPs, generally has declined to commit itself to responding to written comments. In meetings with the agency, agency representatives have expressed that the primary reason rulemaking takes as long as it does is the development, by the agency, of responses to written comments. FDA does not wish to undertake that burden with respect to guidance documents.

According to FDA, however, responses to comments take so long to formulate because those responses become an official part of the rulemaking record, and a big part of any litigation challenging the validity of regulations. Therefore, the responses need to be written carefully and must involve review by the Office of Chief Counsel, among others. Guidance, as opposed to rules adopted through rulemaking, ordinarily cannot be challenged in litigation. As a result, were the agency to commit to responding to comments on guidance, the burden would be substantially less than responding to comments in the rulemaking context.

Furthermore, FDA and its regulated industries may derive significant benefits from responses to comments on guidance documents. First, and perhaps most importantly, these responses serve as important drafting history. Members of the regulated community routinely refer to the agency's responses to comments made in the context of rulemaking proceedings to better understand the rules. FDA's responses show the basis for the agency's thinking and how the agency deals with specific issues raised by members of the public, thereby clarifying the rules considerably. FDA responses to comments on guidance documents would serve a similar function.

Second, responses show that the agency is paying attention to the public comments, spur dialogue, and thus encourage future comments.

Third, responding to comments has the psychological benefit of convincing the public that the agency has legitimate positions. This increases the likelihood of acceptance of the rules as fair and enhances compliance by the regulated community.

As in rulemaking, we are not proposing that the agency provide detailed written responses to each and every comment, but that the agency at least commit to provide general responses to comments grouped by topic.

V. Substantive Appeal (Proposed § 115(o))

The proposed regulations create an appeal process in circumstances where the procedural requirements of the GGPs have not been followed. (Proposed 21 CFR § 10.115(o)). The proposed regulations, however, do not identify an appeal process in instances of disagreement with the substance of the guidance. FDA should cross-reference the normal appeal process for agency decisions (21 CFR § 10.75) to make it clear that § 10.75 applies to disagreements regarding the substantive content of guidance documents.

VI. Guidelines (Proposed changes to existing § 10.90(b))

Several years ago, FDA proposed to eliminate "guidelines" (as opposed to "guidance") from its administrative processes because the defining characteristic of guidelines under 21 C.F.R. § 10.90(b) is that they are binding on the agency. 57 Fed. Reg. 47,314 (October 15, 1992). FDA proposed doing away with guidelines because the agency argued that the guideline process is unlawful in that the only way to bind FDA, according to the agency, is through official rulemaking. That controversial proposal never advanced beyond the original proposal.

Now, FDA is very subtly doing the same thing under the guise of adopting a uniform guidance process, without acknowledging the earlier controversy (or even acknowledging that the agency already proposed this change in 1992). In the GGP proposed rule, the agency is attempting to eliminate guidelines, and with it, their binding effect.

For the most part, this issue is moot because FDA has simply chosen to no longer adopt guidelines. It may remain a problem, however, to the extent that past guidelines lose their binding nature under the current proposal. Many companies may still rely on some of these guidelines. Therefore, FDA should clarify whether or not it intends to abide by the requirements of those guidelines.

VII. Draft Guidance Documents (Proposed § 115(g)(1)(i))

FDA encourages stakeholders to submit draft guidance documents. These proposals can serve as useful starting points for the agency in the development of agency guidance documents. Furthermore, such proposals can save FDA significant amounts of time and resources.

Presently, few in the industry bother anymore to submit draft guidance documents to FDA because their development can be resource intensive. While the reason behind the lack of proposals may be simply a matter of limited resources, industry members also are concerned that submitting draft guidance documents is a waste of time and effort because FDA often fails to respond to these proposals in any tangible way.

For reasons similar to our suggestion that FDA respond to comments on its guidance, we suggest that FDA commit to responding to draft guidance documents submitted by industry. FDA should tell stakeholders that expend the time and effort to propose a draft guidance what the agency

liked or disliked about the proposal. This topic should also be the subject of continued dialogue on the nature of the problem and potential solutions.

VIII. Use of the Internet

In 1995, when the movement to develop the GGPs began, the Internet had yet to become the communication tool that it is today. Now that communication via the Internet has become commonplace, FDA should allow — and even encourage — as much electronic communication as possible between itself and the regulated industries. There are at least two instances where that should be addressed.

A. Submission of Comments (Proposed § 115(h))

The proposed regulations contemplate submitting hard copies of comments on guidance documents only via regular mail to FDA's Dockets Management Branch. Restricting comments to this method of communication seems unnecessary given the informality of the guidance process as compared to rulemaking. We suggest that FDA develop a mechanism that also allows commentors to send comments to the Dockets Management Branch by e-mail and, at the same time, copy by e-mail the particular FDA office responsible for developing the guidance. Logistically, this is the most efficient way to communicate comments to FDA. It also would encourage participation by many people who now are routinely communicating electronically rather than via traditional mail.

B. Expanding Use of the Internet Website Generally (Proposed § 115(f), (g) and (n))

FDA should consider making greater use of its Internet site in posting, for example, the comprehensive list of guidance documents, quarterly updates, announcements of draft and final guidance and the agency's guidance development agenda. We do not believe it is necessary for FDA to publish such materials in the *Federal Register,* in addition to posting them on the web.

IX. Collaborative Collection of Patient and Provider Input (Proposed § 115(g))

Sound policy is best developed based on a complete factual record. Limited resources, however, prevent FDA from gathering necessary input from all of the various stakeholders who may wish to contribute. Doctors and patients provide a particular challenge because most do not read the *Federal Register* on a regular basis or even scout the FDA website.

We propose setting up a mechanism in § 115(g) whereby companies can fund a market research initiative that would permit the agency — through questionnaires, focus groups, and other market research techniques — to obtain input on proposed FDA policy directly from patients, doctors and other stakeholders. In doing so, the industry would want input into the form and structure of the questionnaire (or other research mechanism) to ensure that it is appropriate and likely to produce useful data.

Such an initiative would not only involve a sharing of resources, but also a sharing of intellect between industry and FDA to ensure that this "market research" is done appropriately. The result would be data that FDA and industry both had a hand in developing and that will serve as the basis for policy development ultimately expressed in guidance documents.

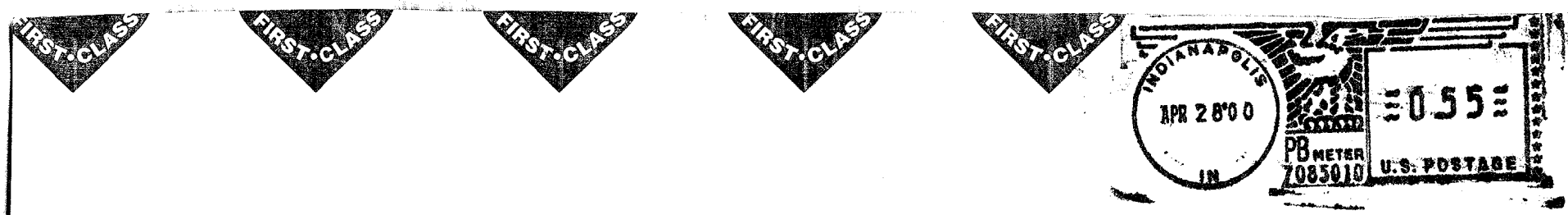
Conclusions

We appreciate the opportunity to comment on FDA's proposed regulations codifying its policies and procedures for the development, issuance, and use of guidance documents. We also look forward to continuing the relationship with FDA that has brought us to this point. Continued cooperative efforts between FDA and its regulated industries can only further improve both agency and industry efforts to better serve the American public.

Very truly yours,

Bradley Merrill Thompson/tw

Bradley Merrill Thompson



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